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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,445	10/15/2003	R. Craig Blaschke	549000243CPB	6865

27572 7590 07/20/2006

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EXAMINER

BUI, LUAN KIM

ART UNIT	PAPER NUMBER
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3728

DATE MAILED: 07/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/686,445

Applicant(s)

BLASCHKE ET AL.

Examiner

Luan K. Bui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-19 and 24-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13-19 is/are allowed.
- 6) ☒ Claim(s) 1, 4, 5, 7-12 and 24-33 is/are rejected.
- 7) ☒ Claim(s) 2, 3 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Applicant indicates that the amended claim 11 including all the limitations of the base claim and any intervening claims is noted. This statement is not correct because the amended claim 11 does not include the limitations of the canceled claim 6. However, claim 11 would be allowable if Applicant amends claim 11 to include the limitations of the canceled claim 6 in response to this Office Action.

Specification

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of 37 CFR 1.71(a)-(c):

(a) The specification must include a written description of the invention or discovery and of the manner and process of making and using the same, and is required to be in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which the invention or discovery appertains, or with which it is most nearly connected, to make and use the same.

(b) The specification must set forth the precise invention for which a patent is solicited, in such manner as to distinguish it from other inventions and from what is old. It must describe completely a specific embodiment of the process, machine, manufacture, composition of matter or improvement invented, and must explain the mode of operation or principle whenever applicable. The best mode contemplated by the inventor of carrying out his invention must be set forth.

(c) In the case of an improvement, the specification must particularly point out the part or parts of the process, machine, manufacture, or composition of matter to which the improvement relates, and the description should be confined to the specific improvement and to such parts as necessarily cooperate with it or as may be necessary to a complete understanding or description of it.

2. The specification is objected to under 37 CFR 1.71, as the specification, as originally filed, does not provide support for the new matter as now claimed. The specification as filed does not provide support for "a member selectively disposed between the first and second container ..." as in claim 24 and "the member comprises a plunger having a selectively

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removable member” as in claim 31, because the plunger does not disposed between the first and second container or “to selectively inhibit or allow the reconstitution fluid to flow from the first container to the second container” as in claim 24.

3. Claims 24-33 are finally rejected under 35 USC 112, first paragraph, for the reasons set forth in the objection to the specification.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 5, 10, 11 are finally rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrases “said tubular body” and “said first and second cavities” in claim 5 and “said plunger” in claim 11 lack proper antecedent basis. In claim 10, the phrase “further comprising a reconstitution liquid” should be changed to --said reconstitution liquid--.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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7. Claims 1 and 12 are finally rejected under 35 U.S.C. 102(b) as being anticipated by Lamborne et al. (6,073,759; hereinafter Lamborne'759). Lamborne'759 discloses a system comprising a container (10) defining a first cavity (46) inherently capable of receiving a liquid and a syringe (12) having a body (14) and a plunger (24) disposed within the first cavity (Figures 4-6). The syringe body of Lamborne'759 is inherently capable of to be a vacuum reservoir and to hold orthopedic material. The syringe of Lamborne'759 is inherently capable of holding orthopedic material selected from the group consisting of allograft and xenograft. Lamborne'759 further discloses a mechanism (30) configured to restrict movement of the plunger to substantially retain a vacuum in the syringe.

8. Claims 1, 12, 24, 31 and 32 are finally rejected under 35 U.S.C. 102(b) as being anticipated by Mueller (4,878,903). Mueller discloses a system (10) comprising a container (16) defining a first cavity (46) inherently capable of receiving a liquid and a syringe (24) having a body (29) and a plunger (27) disposed within the first cavity (Figures 1-2). The syringe body of Mueller is inherently capable of to be a vacuum reservoir and to hold orthopedic material. The syringe of Mueller is inherently capable of holding orthopedic material selected from the group consisting of allograft and xenograft. Mueller further discloses a mechanism (28) configured to restrict movement of the plunger to substantially retain a vacuum in the syringe (column 3, lines 8-9). To the extent that the Examiner can determine the scope of claims 24, 31 and 32, Mueller discloses a member (26) selectively disposed between the first and second container and the

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member configured to selectively inhibit or allow the reconstitution fluid to flow from the first container to the second container

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 4, 5 and 7-10 are finally rejected under 35 U.S.C. 103(a) as being unpatentable over Lamborne et al. (6,073,759; hereinafter Lamborne'759) in view of Raulerson (5,045,065). Lamborne'759 discloses the system as above having all the limitations of the claims except for the plunger comprises at least one through passage. Raulerson shows a syringe (12) comprising a plunger (14) having at least one through passage (27, 32) and a plunger seal (36) having an aperture (27) which is considered equivalent to a gas permeable membrane as claimed. It would have been obvious to one having ordinary skill in the art in view of Raulerson to modify the plunger of Lamborne'759 so the plunger comprises at least one through channel/passage to provide more convenience for the user when using the syringe.

11. Claims 26-33 are finally rejected under 35 U.S.C. 103(a) as being unpatentable over Mueller (4,878,903) in view of Smith (6,286,670). To the extent that the Examiner can determine the scope of the claims, Mueller discloses the system as above having all the

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limitations of the claims except for the container comprises a second cavity and a coupling portion defined between the first and second cavities. Smith teaches a system (50) comprising a container (52) having a first and second cavities (74, 76) and a coupling portion such as a clamp (54, 78, 80) defined between the first and second cavities (Figures 1-2). It would have been obvious to one having ordinary skill in the art at the time the invention was made in view of Smith to modify the container of Mueller so the container comprises a second cavity and a coupling portion/clamp defined between the first and second cavities for separating the two cavities prior of mixing.

Allowable Subject Matter

12. Claims 2 and 3 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. Claims 13-19 are allowed.

14. Claim 11 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Response to Arguments

Applicant's arguments with respect to 5/15/2006 have been considered but are deemed to be moot in view of the new grounds of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luan K. Bui whose telephone number is 571-272-4552. The examiner can normally be reached on 8:30-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on 571-272-4562. **The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for Formal papers and After Final communications.**

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

lkb
July 6, 2006

A handwritten signature in black ink, appearing to read 'Luan K. Bui', with a long horizontal stroke extending to the right.

Luan K. Bui
Primary Examiner
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